

15 July 2021

# Creso Pharma completes acquisition of established Canadian psychedelics company Halucenex Life Sciences Inc.

# **Highlights:**

- Completion of acquisition provides Creso Pharma with access to the emerging global market for psychedelic medicines estimated to be worth up to US100Bni
- Halucenex to progress phase II clinical trial to test the efficacy of psilocybin when used to treat Post Traumatic Stress Disorder (PTSD)
- PTSD therapeutics market expected to grow to US\$10.5Bn by 2025ii
- Additional synergies being explored to position the company to capitalise ahead of proposed merger with Red Light Holland ("RLH")
- Creso Pharma to leverage expertise of Halucenex and RLH management to expedite product development initiatives, ongoing R&D and potential market entries
- Halucenex's operation progress continues USP 61 test protocols complete providing additional validation of psilocybin compounds ahead of Clinical Trial Application
- USP 62 test protocols to test product degradation now underway expected to be completed in coming weeks
- Halucenex to progress Clinical Trial Application next month, prior to receipt of Controlled Drugs and Substances Dealer's License from Health Canada in a push to expedite clinical trial process
- COVID-19 has further highlighted mental health effects and the potential for alternative solutions such as Psychedelic assisted therapy<sup>iii</sup>
- Halucenex will play a crucial role in the proposed Merger between Creso Pharma and RLH in the creation and growth trajectory of The Highbrid Lab
- · Further positive updates from Halucenex expected in the short term
- Creso Pharma is the now the only ASX listed company, and one of a few globally, operating in Cannabis and Psychedelic R&D and therapies and treatments

**Creso Pharma Limited (ASX:CPH, FRA:1X8) ('Creso Pharma' or 'the Company')** is pleased to advise that it has completed the acquisition of established Canadian psychedelics company Halucenex Life Sciences ("Halucenex").

The completion of the transaction follows considerable due diligence undertaken by Creso Pharma. The acquisition marks an important milestone, as it provides direct access to the emerging psychedelic-assisted psychotherapy (PAP) sector and unlocks a number of opportunities for the Company in the near term and following Creso Pharma's potential merger with Red Light Holland (refer ASX announcement: 17 June 2021).

For further details on the terms of the Halucenex acquisition please refer to announcement 15 March 2021 and the notice of meeting 21 May 2021. Shareholders approved the acquisition at the Company's annual general meeting held on 24 June 2021.

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# Current strategic opportunities and business synergies post merger:

The acquisition of Halucenex unlocks a number of near term opportunities and access to additional lucrative market verticals. Recently, there has been a growing body of evidence demonstrating that psychedelic medicines are safe and non-addictive when used in medical settings. In a number of clinical trials completed in recent years, psychedelic-assisted psychotherapy has produced some significant, long-lasting clinical outcomes for individuals living with mental health conditions.

The potential for psychedelic-assisted therapy to be commercialised as a safe and effective treatment provides a solution to the growing global mental health crisis. Mental health conditions remain significantly undertreated, with mainstream treatments considered to be ineffective with major side effects. Surveys have indicated that less than half of individuals with a mental illness do not receive any form of treatment<sup>iv</sup>.

In the near term, Halucenex will focus on progressing clinical trials to assess the safety and efficacy of PAP using psilocybin to treat mental illness, with the aim of becoming a clinical drug pipeline provider. The Company will also progress complementary business strategies including R&D to produce novel proprietary formulations of psychedelic compounds and exploring the interactions between natural and synthetic psilocybin derivatives to accumulate intellectual property on the entourage effects of naturally sourced psilocybin.

Creso Pharma will also work closely with Red Light Holland to explore additional opportunities through Halucenex. Red Light Holland has recently extended its Letter of Intent (LOI) with Mera Life Sciences and continues discussions regarding a previously announced potential investment in St. Vincent and the Grenadines, which is anticipated to be a part of the combined company's applied science platform, following completion of the proposed merger (refer ASX announcement: 17 June 2021). Completion of the merger remains subject to a number of conditions including Creso and Red Light Holland shareholder approval.

In addition, both parties plan to leverage the significant pharmaceutical expertise of Creso Pharma and Halucenex's management team through all applied science activities to use findings to continuously update and expand Red Light Holland's iMicrodose app, and consider introducing psychedelic assisted therapy retreats where legally permissible.



**Images:** Halucenex conceptual product dosage packaging

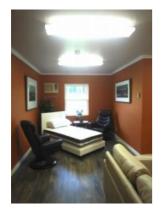


# Halucenex's recent operational progress:

Halucenex has made further operational progress towards the commencement of its proposed phase II clinical trial. Most recently, management have completed all USP 61 requirements, which provide considerable validation for the use of its GMP grade psilocybin.

The USP 61 test provides enumeration of mesophilic bacteria and fungi that may grow under aerobic conditions. This test provides the total number of aerobic organisms, yeast, and mould present within a sample. The sample is typically diluted, plated, and then incubated with results used to determine whether or not compounds can be used for human testing. The Company advises that Halucenex has completed this testing phase and will now progress the USP 62 test, which will highlight the shelf life of its psilocybin samples, as well as provide additional validation. USP 62 test protocols are currently underway and will be completed in the coming weeks.

Following completion of these tests, Halucenex will be positioned to apply for Clinical Trial Authorisation (CTA) and subject to the receipt of its of its Controlled Drugs and Substances Dealer's License (Dealer's License) from Health Canada commence a phase II clinical trial into the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder (PTSD). The Company can apply for its CTA prior to the receipt of its Dealer's License from Health Canada, expediting its clinical trial process.







Images: Established 16,000 sq ft treatment facilities in Nova Scotia, Canada

# **Commentary:**

**Halucenex Founder & CEO Bill Fleming said**: "We are very excited to become part of the Creso Pharma group, particularly at an exciting stage of the Company's growth.

"Halucenex has undertaken a strategic and measured approach to date and we are confident that with the resources Creso Pharma can provide, we will be able to expedite our clinical trial and potential product development strategies which will unlock significant value for shareholders.

"Importantly, Halucenex continues to track very well form an operational standpoint. Recent USP 61 results have highlighted that our GMP grade psilocybin is now validated ahead of a clinical trial. We expect USP 62 testing to be finalised before the end of the month, which will allow us to take another step towards the commencement of our phase II clinical trial."

**Non-executive Chairman Adam Blumenthal said:** "Completing the acquisition Halucenex is a major milestone for Creso Pharma and we will now aggressively pursue a number of near term value creation strategies through the subsidiary and in preparation of the proposed merger with Red Light Holland.

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"This acquisition has allowed Creso Pharma to emerge as a best-in-class provider of cannabis, cannabinoids and alternative psychedelics solutions to meet a large and unmet demand to improve mental health and wellbeing.

"We look forward to leveraging Halucenex's expertise in this space to progress the proposed phase II clinical trial, while simultaneously exploring opportunities with Red Light Holland, which will leave all parties well positioned to capitalise on another lucrative vertical."



#### Clinical trials

Clinical trials will focus on the treatment of anxiety and other mental health challenges such as depression and PTSD



#### Developing IP for a formulation of synthetic psilocybin

Natural psilocybin is less compatible in clinical settings due to inconsistency of potency and therefore dosage, producing synthetic psilocybin in-house will replace third-party supply agreements and potentially allow Halucenex to supply to other distributors and practitioners



#### **Delivery methods**

Halucenex plans to develop products across a range of delivery methods such as psilocybin-infused capsules and tinctures



#### Agile business plan

Fast track to commercialisation via the Veterans market will deliver cash flow early, while maintaining a flexible business plan will allow the company to adapt to the changing regulatory environment

Image: Halucenex's long-term strategy

-Ends-

## **Authority and Contact Details**

This announcement has been authorised for release by the Board of Creso Pharma Limited.

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#### **About Creso Pharma**

Creso Pharma Limited (ASX:CPH) brings the best of cannabis to better the lives of people and animals. It brings pharmaceutical expertise and methodological rigor to the cannabis world and strives for the highest quality in its products. It develops cannabis and hemp derived therapeutic,

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nutraceutical, and life style products with wide patient and consumer reach for human and animal health.

Creso Pharma uses GMP (Good Manufacturing Practice) development and manufacturing standards for its products as a reference of quality excellence with initial product registrations in Switzerland. It has worldwide rights for a number of unique and proprietary innovative delivery technologies which enhance the bioavailability and absorption of cannabinoids. To learn more please visit: www.cresopharma.com

#### About Halucenex Life Science:

Halucenex is a life sciences development company with a focus on researching novel psychedelic compounds, developing and licensing psychedelic compounds for the pharmaceutical and nutraceutical markets, and conducting clinical trials on the medical benefits of psychedelic medicine. Halucenex operates a 6000 sq. ft. medical facility in Windsor, Nova Scotia with 6 treatment rooms and a secure laboratory dedicated to performing psychedelic-assisted psychotherapy and clinical research. Halucenex intends to maintain control over all aspects of the product development process – mycological research, extraction technology, and synthetic formulation as well as drug delivery technologies, psychedelic-assisted psychotherapy and regulatory affairs. www.halucenex.com

# **Forward Looking statements**

This announcement contains forward-looking statements with respect to Creso and its respective operations, strategy, investments, financial performance and condition. These statements generally can be identified by use of forward-looking words such as "may", "will", "expect", "estimate", "anticipate", "intends", "believe" or "continue" or the negative thereof or similar variations. The actual results and performance of Creso could differ materially from those expressed or implied by such statements. Such statements are qualified in their entirety by the inherent risks and uncertainties surrounding future expectations. Some important factors that could cause actual results to differ materially from expectations include, among other things, general economic and market factors, competition and government regulation.

The cautionary statements qualify all forward-looking statements attributable to Creso and persons acting on its behalf. Unless otherwise stated, all forward-looking statements speak only as of the date of this announcement and Creso has no obligation to up-date such statements, except to the extent required by applicable laws.

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<sup>&</sup>lt;sup>1</sup> Canaccord Genuity US Equity Research - Biotechnoloogy Industry Update - Psychedelic-derived medicines and therapies: a follow-up

<sup>&</sup>lt;sup>ii</sup> Credence Research Post-Traumatic Stress Disorder Therapeutics Market - Growth, Future Prospects and Competitive Analysis, 2018-2026

iii https://www.sbs.com.au/news/the-feed/could-psychedelic-drugs-help-people-with-mental-illness-cope-during-covid-19

iv SAMSHA. National Survey on Drug Use and Health. 2007 from http://www.oas.samhsa.gov/NSDUHlatest.htm